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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,356	06/25/2001	Thomas Mathew Cocks	DAVII22.001A	7835
20995	7590	12/28/2004	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			LANDSMAN, ROBERT S	
2040 MAIN STREET			ART UNIT	
FOURTEENTH FLOOR			PAPER NUMBER	
IRVINE, CA 92614			1647	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/787,356

Applicant(s)

COCKS ET AL.

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-9 and 20-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5-9, 20-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *1. Formal Matters*

- A. The Amendment dated 10/5/04 has been entered into the record.
- B. Claims 1, 2, 5-9 and 20 were pending. New claims 21-23 have been added. Therefore, claims 1, 2, 5-9 and 20-23 are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

### *2. Specification*

- A. The Brief Description of Figure 5 remains objected to since the word "shows" should not be plural. i.e. "Figure 5A and 5B show[s]"
- B. The Brief Description of Figure 8 remains objected to since it should begin by reciting "Figures 8A-8D"
- C. The Brief Description of Figure 15 remains objected to since it should begin by reciting "Figures 15A and 15B"
- D. The Brief Description of Figure 19 remains objected to since it should begin by reciting "Figures 19A-19D"
- E. The objection to Table 3 has been withdrawn since the application is now in sequence compliance

### *3. Claim Objections*

- A. The syntax of claim 1 could be amended by amending the phrase "peptide analog thereof in which one or more amino acids is replaced with non-natural amino acid" to "peptide analog thereof in which one or more amino acids [is] are replaced with non-natural amino acids."

### *4. Claim Rejections - 35 USC § 112, second paragraph*

- A. Claims 1, 2, and 5-9 remain rejected under 35 USC 112, second paragraph, for the reasons already of record on page 3 of the Office Action mailed 4/1/04. Though claim 1 does now recite an identifiable endpoint, the endpoint does not relate back to the preamble. The preamble recites "a method for prophylaxis or treatment of inflammation" whereas the endpoint recites "mediating relaxation of said airway." Either the preamble should be amended to recite, for example, "...treatment of inflammation by

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mediating relaxation of an airway” or the endpoint should recite, for example, “relaxation of said airway, thereby providing prophylaxis or treatment of inflammation of said airway.”

B. The rejection of claim 5 under 35 USC 112, second paragraph, has been withdrawn in view of Applicants’ amendment to provide antecedent basis for “airway disease condition.”

C. The rejection of claim 20 under 35 USC 112, second paragraph, has been withdrawn in view of Applicants’ amendment to the conclusion of the claim.

D. Claim 20 is confusing since it is not clear how it is known that a compound which activates PAR would be guaranteed to be effective in treating inflammation. It is suggested that the claim be amended to recite, for example, “is identified as capable of being useful...”

E. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The claim references a Table, which is not permitted.

#### ***5. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement***

A. Claims 1, 2 and 5-9 remain rejected and new claim 23 is also rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 4-5 of the Office Action mailed 4/1/04. The part of the rejection regarding the scope of treating all types of inflammation has been withdrawn in view of Applicants’ arguments that Examples 14 and 15 demonstrate the use of these compounds for inflammation and Applicants’ submission of references demonstrating that the specification uses art-accepted models as well as Applicants’ submission of a Declaration by Dr. Cocks under 37 CFR 1.132 which discusses the relationship between inflammation (especially paragraphs 88-12).

However, the scope of the claims remains excessive with regard to Applicants claiming in claim 1 “peptide analog thereof in which one or more amino acids is replaced with non-natural amino acid.” Applicants have removed the term “agent.” However, the breadth of the claim is excessive since **every amino acid in SEQ ID NO:2 could be replaced with a different non-naturally occurring amino acid.** Applicants have not provided and guidance or working examples of peptides in which a large percent number of residues have been replaced. Applicants are, therefore, claiming a method using a peptide

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which potentially has no structural relationship to SEQ ID NO:2, the peptide of the invention. Since the claims are not limited to "consisting of" language, which will likely not remedy the situation, but recite "comprising" this would mean that any peptide or protein which activates PAR would be encompassed by the claim regardless of having any structural similarity to SEQ ID NO:2. It would not be predictable to the artisan which amino acids could be altered to non-natural amino acids to retain function, which would include replacing every amino acid of SEQ ID NO:2.

Regarding claim 23, the claim recites "a peptide derivative thereof having similar biological activity to SLIGRL..." Again, Applicants have not provided sufficient guidance or working examples as to what changes can be made to SLIGRL and retain the structural and functional characteristics of SLIGRL, nor would it be predictable to the artisan what changes to make given this lack of guidance. There are no structural requirements on the peptide which differs from SLIGRL.

Therefore, in summary, the breadth of the claims remains excessive with regard to Applicants claiming methods using peptides comprising the sequence of SEQ ID NO:2 in which every amino acid could potentially be replaced. Applicants do not provide guidance or working examples of peptides in which a large number of amino acids have been replaced, nor is it predictable to the artisan which amino acids could be replaced to retain the structural similarities to SEQ ID NO:2 and retain function. Therefore, the Examiner maintains that undue experimentation would be required to practice the invention as claimed.

B. Claim 2 remains rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 5-6. Applicants argue that they use A549 cells from human carcinoma. However, it is not clear if this is an art-accepted model for studying treatment of airway inflammation **in humans in vivo**. An article demonstrating the use of these cells as an accepted model for airway inflammation would obviate this rejection.

#### ***6. Claim Rejections - 35 USC § 112, first paragraph – written description***

A. Claims 1, 2 and 5-9 remain rejected and new claim 23 is also rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 6-7 of the Office Action mailed 4/1/04. The part of the rejection regarding claim 20 has been withdrawn in view of Applicants' amendments to the claims. Applicants argue that the newly added limitations are sufficient to provide adequate description to the artisan and that numerous examples of non-natural amino acids have been described.

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These arguments have been considered, but are not deemed persuasive. However, there remains a lack of written description with regard to Applicants claiming in claim 1 "peptide analog thereof in which one or more amino acids is replaced with non-natural amino acid." Applicants have removed the term "agent." However, **every amino acid in SEQ ID NO:2 could be replaced with a different non-naturally occurring amino acid.** Applicants have not provided adequate written description of peptides in which a large percent number of residues have been replaced. Applicants are, therefore, claiming a method using a peptide which potentially has no structural relationship to SEQ ID NO:2, the peptide of the invention. Since the claims are not limited to "consisting of" language, which will likely not remedy the situation, but recite "comprising" this would mean that any peptide or protein which activates PAR would be encompassed by the claim regardless of having any structural similarity to SEQ ID NO:2.

Regarding claim 23, the claim recites "a peptide derivative thereof having similar biological activity to SLIGRL..." Again, Applicants have not provided adequate written description as to what changes can be made to SLIGRL and retain the structural and functional characteristics of SLIGRL.

#### ***7. Claim Rejections - 35 USC § 112, first paragraph - new matter***

A. Claims 1, 2, 5-9, 20 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Though Applicants have shown that non-natural amino acids can be substituted, the Examiner cannot find support for the breadth of the limitation in claim 1 of "in which one or more amino acids is replaced." Applicants are required to show exactly where in the specification this support can be found.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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***Advisory information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on M-Th 9 AM-6 PM (eastern); alt F 9 AM-6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



ROBERT LANDSMAN  
PATENT EXAMINER

Robert Landsman  
Primary Examiner  
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